Response to Questions

RFP No. NIH-NIAID-DMID-PR2004-01

'Neutralizing Monoclonal Antibodies for Type A Botulinum Neurotoxins'

The referenced RFP is amended as follows:

Section I.2. Authorized Substitutions of Clauses is revised to add FAR Clause 52.215-20, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data.

Section I.3. Additional Contract Clauses is revised to remove item (6) FAR 52.237-10, Indemnification of Uncompensated Overtime (OCTOBER 1997).

Below are the Questions and Answers in response to the referenced RFP:

Q1. How does USG propose to deal with intellectual property issues, as they relate (i) to contractor-owned IP and (ii) to IP required for performance?

Answer: Bayh-Dole Act pertains to IP developed by the contractor under a USG contract (35 USC 200 to 212). The contract will contain the Authorization and Consent Clause (FAR 52.227-1).

Q2. Please explain the rationale for the scope of work, which as noted in the RFP is inadequate to file an IND. Is it USG's intent to award follow-on modules based on progress, or to have other contractors or NIAID undertake the necessary additional work? Can you indicate what, if any, intent USG has with respect to future product purchase?

Answer: The purpose of the contract is to manufacture sufficient quantity of cGMP material to be used in future preclinical and clinical proof-of-principle studies.

Q3. Is it responsive to the proposal to file a drug master file with FDA rather than write a CMC section for NIAID?

Answer: The CMC is the required deliverable.

Q4. Are the 7 g of each of 3 mAbs intended for human use?

Answer: They are intended for use in preclinical and Phase I clinical studies.

Q5. Does provision of 7 g of each of 3 mAbs to NIH trigger any royalty payments due to the Cabilly patent or any other relevant patent?

Answer: Bayh-Dole pertains to IP developed by the contractor under a USG contract (35 USC 200 to 212). The contract will contain the Authorization and Consent Clause (FAR 52.227-1).

Q6. Page 23 under Technical Discussions section 4) Facilities- a letter is required agreeing to a pre-award cGMP audit. A potential partner has performed cGMP manufacturing while part of another facility. They may not have all components of cGMP established in their new facility at the time of the award, but plan to be cGMP compliant prior to this stage of the timeline. Is this timing acceptable or does it preclude consideration for this RFP?

Answer: It does not preclude consideration for the contract. The offeror should include a letter that offers access to audit the facility even if it acknowledges not having reached cGMP compliance at the time of award.

Q7. Page 5 of 30. The deliverables include the provision of seven grams of GMP bulk drug substance for each of three monoclonal antibodies at a concentration of 30 mg/ml. What is the intended use for this material. Will this material be used in humans?

Answer: The cGMP material will be used in IND supporting preclinical and Phase I clinical studies.

Q8. The schedule set forth in the RFP does not allow sufficient time for negotiation with the University of California regarding acquisition of the monoclonal antibodies and negotiation of subcontracts for critical aspects of the project. Will the Agency consider amending the RFP to extend the schedule 8 weeks to allow for these necessary activities ?

Answer: There will not be an extension of the receipt date.